



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1411]

Drug Product Tracing: The Effect of Section 585 of the Federal Food, Drug, and Cosmetic Act--Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Drug Product Tracing: The Effect of Section 585 of the FD&C Act--Questions and Answers." FDA is issuing this guidance to assist industry and State and local governments in understanding the effects of the uniform national policy set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) that was added by the Drug Supply Chain Security Act, which was enacted on November 27, 2013. This guidance is intended to help industry and States understand the law as it is currently in effect and clarify its effect on State product tracing. This guidance finalizes the draft guidance entitled "The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers" issued on October 8, 2014.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-1411 for "Drug Product Tracing: The Effect of Section 585 of the FD&C Act--Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm.7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Drug Product Tracing: The Effect of 585 of the FD&C Act--Questions and Answers." Title II of the Drug Quality and Security Act (Pub. L. 113-54), which is also referred to as the Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013, established a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to provide, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third-party logistics providers (3PLs); the Agency is publishing a proposed rule with respect to those standards concurrently with this final guidance. Section 585 of the FD&C Act (21 U.S.C. 360eee-4) sets forth a uniform national policy preempting States from establishing or continuing in effect certain standards and requirements. The guidance is intended to (1) help industry and States understand the law as it is currently in effect and (2) clarify the effect of section 585(a) on State product tracing.

This guidance finalizes the draft guidance entitled "The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers" issued on October 8, 2014 (79 FR 60853). The

draft guidance covered section 585(a) and (b) of the FD&C Act. This guidance does not cover the effect of section 585(b) of the FD&C Act, given that section 585(b) is addressed in the preamble to the proposed rule with respect to the standards for licensing wholesale distributors and 3PLs, published elsewhere in this issue of the *Federal Register*. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the removal of the discussion of the effect of 585(b) of the FD&C Act. The title of the guidance has been updated to reflect this change in content. In addition, editorial changes were made to improve clarity

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Drug Product Tracing: The Effect of 585 of the FD&C Act--Questions and Answers." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.